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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,164	06/19/2003	Sudeep M. Kumar	090900-0158	9722

26371 7590 04/21/2008
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EXAMINER	
TURK, NEIL N	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,164	KUMAR ET AL.	
	Examiner	Art Unit	
	NEIL TURK	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 27th, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10-23,25-27,29-40 and 42-61* is/are pending in the application.

4a) Of the above claim(s) *59-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on November 27th, 2007. Claims 1-6, 8, 10-23, 25-27, 29-40, and 42-61 are pending. Claims 7, 9, 24, 28, and 41 have been cancelled. Claims 59-61 have been withdrawn from consideration as being drawn to a non-elected invention.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 27th, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27, 29-36 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the structural

relationship of the working electrode to the counter electrode and the counter electrode with the light detector. The claims recite a working electrode and counter electrode, and a light detector and/or transparent portion that is in optical registration with the working electrode. However, it is unclear how the working electrode is structurally related to the counter electrode and further it is unclear how the counter electrode is related to the light detector and/or transparent portion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the

obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 22, 23, 37-40, 42-53, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama (5,993,740) in view of Pyke (5,591,321).

Niyama discloses an electrochemiluminescence cell and method of its use. Niyama discloses that the cell includes working electrode 15, counter electrodes 16a, 16b, window 22 and light sensor 19 (photodetector, pmt, photodiode)(abstract, lines 44-49, col. 3; lines 48-67, col. 7; col. 8; figs. 2-4). Niyama discloses that the electrodes may be made of such materials as platinum, iridium, tungsten and alloys there of such that these materials prevent wear and corrosion from reaction and reagents flowing on the electrode surfaces (lines 23-42, col. 5); Niyama shows in figures 5A-F forms of models including a magnetic particle 40 (trapped in the chamber by way of a magnet over the working electrode, lines 62-67 col. 4), first reagent 44, TSH 47 as the analyte in the sample, second reagent 48, reaction product 54 and TPA as the attractant in the buffer solution. Niyama also discloses that TPA (tripropylamine) is the attractant contained in the buffer solution, which is reduced upon application of a voltage so as to excite the label material and has a pH of about 7.4, and additionally the second reagent 48 has fixed to $Ru(bpy)_3$ (ruthenium-tris-bipyridine) as the label material (lines 44-48, col. 7; lines 65-67, col. 11; lines 1-13, col. 12, fig 5A-F).

Niyama does not disclose a working electrode or counter electrode that comprises a platinum alloy with a second element other than platinum or rhodium having a 5 to 50 (and also 10 to 30%) weight percent, nor an iridium alloy with a second element from 5 to 50% weight percent.

Pyke discloses a sensor electrode of a Pt/Ir alloy, consisting of 5 to 90% iridium, as well as Pt30Ir (30% iridium) (lines 4-12, col. 11). Examiner asserts Pyke thereby disclsoses both a Pt alloy with an amount of iridium from 5 to 50% weight percent, as well as 10 to 30%, and an Ir alloy with an amount of platinum from 5 to 50%. Further, Pyke recites the percentages as atomic weights, and Examiner asserts such that Pt (AW: 195) and Ir (AW: 192) (within around 1% of each other) the converted weight percentages will still result in the necessary compositions as required by the claims.

It would have been obvious to modify Niyama to include an Pt/Ir alloy electrode containing, for example, 30% iridium, as well as an Ir/Pt alloy with 5 to 50% platinum, as taught by Pyke such that Niyama discloses the use of Pt/Ir and Ir/Pt alloy electrodes and this would provide Niyama with a known composition of Pt/Ir and Ir/Pt alloy electrodes, as well as providing electrodes that are resistant to corrosion and wear as desired by Niyama.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama in view of Chang et al. (5,973,443), hereafter Chang.

Niyama has been discussed above.

Niyama does not disclose a working or counter electrode comprised of a rhodium alloy, with a first weight percent of rhodium and a second weight percent of an element other than rhodium or platinum.

Chang discloses an iridium-rhodium electrode used to minimize erosion and wear resistance, where the rhodium may be greater than 30 weight percent and less than 60 weight percent in the iridium. Examiner asserts such a disclosure points to a rhodium alloy, in which there is a second element (iridium) between 5 and 50%.

It would have been obvious to modify Niyama to include a working or counter electrode of a rhodium-iridium alloy, in which the iridium constitutes 5 to 50% of the alloy, such as taught by Chang in order to supply Niyama with a known electrode alloy composition and further to provide Niyama with a noble metal electrode alloy so as to provide the desired resistance to corrosion and wear, as desired and discussed in Niyama. Examiner asserts that Chang discloses a known electrode composition, of noble metals, which analogously provides the property of resistance to corrosion and wear, as disclosed and desired by Niyama.

Claims 10-19, 25-27, and 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama in view of Pyke as applied to claims 1-6, 8, 22, 23, 37-40, 42-53, and 56-58 above and in further view of Wohlstadter (6,207,369).

Niyama/Pyke does not disclose that the support for the counter electrode is transparent and that the counter electrode is not a mesh or a screen, and includes a

field extending element (further, as a ladder electrode or projections forming an interdigiated array) that traverses the transparent portion.

Wohlstadter discloses an electrochemiluminescent cell and method of its use. Wohlstadter also discloses that commercial ECL assays are performed using a flow cell with a working and counter electrode. Wohlstadter also discloses the use of a waveform generator/potentiostat as a source of electrical energy (lines 4-12, col. 12). Wohlstadter discloses that the cell may have electrodes with field extending structures as shown in figures 6b and 19a-e, and such combinations provide for a constant electric field and supports for the electrodes may be of any material, including transparent materials (lines 1-10, col. 44; col. 42-44). Examiner asserts that such an electrode as disclosed and shown in figures 6b, and 19a,e by Wohlstadter constitutes a ladder electrode and projections forming an interdigitated array by Applicant's definition given in paragraphs 0093 and 0096 of the pre-grant publication (2004/0090168). Examiner further asserts that claim 25's current recitation does not require any reduction of the electrochemiluminescence incident upon the transparent parent, as the recitation,"...reduces...by less than 50%" reads on 0%, which Wohlstadter at least discloses, given the recited field extending element.

It would have been obvious to modify the Niyama/Pyke device to include a transparent support and a counter electrode with a field extending element not of a mesh or screen (and also a a ladder electrode and projections that form an interdigitated array) that transverses the transparent portion of the support such as taught by Wohlstadter in order to provide a counter electrode that provides a constant

electric field and selective transmittance of the generated electrochemiluminescence to the detector and selectively blocks light incident to the detector, and a support of a suitable material to allow light through to observe/detect reactions by optical means.

Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama in view of Crane (3,784,928).

Niyama has been discussed above.

Niyama does not disclose a working or counter electrode comprised of a rhodium alloy, with a first weight percent of rhodium and a second weight percent of an element other than rhodium (and specifically, platinum, as recited in claim 55) from 5 to 50%.

Crane discloses rhodium-platinum alloys as material for anode and cathode electrodes, in which the Rh-Pt alloy electrodes may include 1 to 100 weight percent rhodium (lines 25-47, col. 4).

It would have been obvious to modify Niyama to include a working or counter electrode of a rhodium-platinum alloy, in which the platinum constitutes 5 to 50% of the alloy, such as taught by Crane in order to supply Niyama with a known electrode alloy composition and further to provide Niyama with a noble metal electrode alloy so as to provide the desired resistance to corrosion and wear, as desired and discussed in Niyama.

Claims 1-6, 8, 10-19, 22, 23, 25-27, 30-40, 42-53, and 56-58 are rejected under 35 U.S.C. 103(a) as being obvious over Liljestrand (6,200,531) in view of Niyama and in view of Pyke and in view of Kovacs (5,965,452).

Liljestrand discloses an apparatus for carrying out electrochemiluminescence test measurements. Liljestrand discloses that the prior art includes a flow cell (US Patent No. 5,466,416) that comprises a counter electrode 26, ECL test chamber 28, working electrode 30, transparent 32, and the flow cell 18 includes a main housing 48 formed of a transparent, chemically inert material. Liljestrand also discloses that working electrode 30, counter electrode 26, and counter electrode 34 may consist of electrically-conductive materials such as platinum (lines 7-10, col. 2, fig. 1&2). Liljestrand further discloses that counter electrode 26 is affixed to a side of transparent block 32. Liljestrand discloses that the counter electrode 136 may comprise a mesh or a screen and counter electrode 136 is shaped to fit a counter electrode groove in component 134 and may be “L” shaped or “T” shaped advantageously such that one “arm” of the configuration may be positioned to extend beyond component 142 to provide the provision of electrical energy (lines 58-67, col. 12; lines 1-5, col. 13). Liljestrand also discloses reference electrode 128 is an ECL reference electrode for detecting the voltage level of an assay sample (lines 23-36, col. 12). Liljestrand further discloses that the invention may also include a photodetector, e.g. a photodiode, in optical registration with the electrically-shielded window, the transparent portion of the cell wall and the working electrode (lines 33-36, col. 5). Liljestrand also discloses that a removable magnet is provided for applying a magnetic field to the working electrode (lines 37-42,

col. 5). Liljestrand further discloses that registration of working electrode 140, opening 137, opening 133 (of the counter electrode 136), transparent base 127, aperture 125, conductive window 124, optical filter 123 and light detector 122 is necessary in order to provide optimal transmittance of light from the working electrode to the light detector, and opening 133 functions as an optical element the defines the electrochemiluminescence that may propagate to the light detector. Liljestrand also discloses that the counter electrode may be designed to block undesired light generated in certain regions (lines 41-67, col. 14, fig. 3a). Liljestrand also discloses that electrical energy is supplied to flow cell 120 through working electrode 140 and counter electrode 136 by application of main controller 214 (waveform generator/potentiostat included in main controller 214) to cause the input fluid to electrochemiluminescence (lines 39-42, col. 17; lines 15-23, col. 18).

Liljestrand does not disclose a working electrode or counter electrode that comprises a platinum alloy with a second element other than platinum or rhodium having a 5 to 50 (and also 10 to 30%) weight percent, nor an iridium alloy with a second element (and specifically, platinum) from 5 to 50% weight percent.

Liljestrand also does not disclose a counter electrode with a field extending element, where the counter electrode is not a mesh or screen and the field extending element is a ladder electrode.

Niyama and Pyke have been discussed above.

Kovacs discloses a biological electrode array in which in an embodiment for incorporating optical fluorescence or transmittance detection circuitry into the electrode

matrix 12 it is desirable to provide a slitted or punctuated electrode structure, such as that shown in figure 8(b). Examiner asserts that such an electrode as disclosed and shown in figure 8b by Kovacs constitutes a ladder electrode by Applicant's definition given in paragraph 0096 of the pre-grant publication (2004/0090168). Orifices 56 allow the passage of light through the electrode 52 to the optical detector 50, thus eliminating the need for an external camera and reducing the analysis system cost (lines 30-65, col. 8, fig. 8b). Examiner asserts that claim 25's current recitation does not require any reduction of the electrochemiluminescence incident upon the transparent parent, as the recitation,"…reduces…by less than 50%" reads on 0%, which Kovacs at least discloses, given the recited field extending element.

It would have been obvious to modify Liljestrand to include an Pt/Ir alloy electrode containing, for example, 30% iridium, as well as an Ir/Pt alloy with 5 to 50% platinum, as taught by Pyke in order to provide known compositions of Pt/Ir and Ir/Pt alloy electrodes, so as to provide electrodes that are resistant to corrosion and wear as taught by Niyama, whose disclosure analogously noble metal alloy electrodes and teaches use of such in electrochemiluminescent systems.

It would have been obvious to modify Liljestrand to include a field extending element that is not a mesh or screen such as taught by Kovacs in order to provide a design to the counter electrode which provides selective transmittance of the generated electrochemiluminescence to the detector and selectively blocks light incident to the detector.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liljestrand in view of Niyama and in view of Pyke and in view of Kovacs as applied to claims 1-6, 8, 10-19, 22, 23, 25-27, 30-40, 42-53, and 56-58 above and in further view of Wohlstadter.

Liljestrand/Niyama/Pyke/Kovacs does not specifically disclose that the field extending element comprises projections that form an interdigitated array.

Wohlstadter has been discussed above.

It would have been obvious to modify Liljestrand/Niyama/Pyke/Kovacs to include a field extending element compried of projections that form an interdigitated array such as taught by Wohlstadter in order to provide another structural form of a field extending element that provides selective transmittance of the generated electrochemiluminescence to the detector and selectively blocks light incident to the detector, while also providing a constant electric field.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljestrand in view of Chang.

Liljestrand and Chang have been discussed above.

It would have been obvious to modify Liljestrand to include a working or counter electrode of a rhodium-iridium alloy, in which the iridium constitutes 5 to 50% of the alloy, such as taught by Chang in order to supply Liljestrand with a known electrode alloy composition with a noble metal electrode alloy so as to provide the desired resistance to corrosion and wear.

Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljestrand in view of Crane.

Liljestrand and Crane have been discussed above.

Liljestrand does not disclose a working or counter electrode comprised of a rhodium alloy, with a first weight percent of rhodium and a second weight percent of an element other than rhodium (and specifically, platinum, as recited in claim 55) from 5 to 50%.

It would have been obvious to modify Liljestrand to include a working or counter electrode of a rhodium-platinum alloy, in which the platinum constitutes 5 to 50% of the alloy, such as taught by Crane in order to supply Liljestrand with a known electrode alloy composition of noble metals so as to provide an electrode alloy resistant to corrosion and wear.

Response to Arguments

Applicant's arguments with respect to claims **1-6, 8, 10-23, 25-27, 29-40, and 42-58** have been considered but are moot in view of the new ground(s) of rejection, as discussed above.

Further, Applicant argues that Niyama lists a limited permissible group of alloys for the electrodes of the invention. Examiner asserts that Niyama further discloses that the reason for choosing any such material is to prevent wear and corrosion of the electrode surface (lines 21-29, col. 4). Examiner asserts that one of ordinary skill in the art, in reading Niyama, would understand that materials outside of the group listed in

Niyama would be permissible to modify such a device, as long as such materials provide the desired effect of preventing wear and corrosion to the electrode surface. This can especially be seen in additional prior art documents which form electrodes from noble metal alloys, as noble metals posses such properties, and Niyama's discussion with respect to electrode material and alloys thereof highly focuses on the use of noble metal alloys for the purpose of preventing wear and corrosion to the electrode surface. As rhodium is a material resistant to wear and corrosion as desired by Niyama, as well as being a noble metal, alloying of rhodium with a noble metal (or other material resistant to wear and corrosion) is seen as an obvious modification to one of ordinary skill in the art. As such, these modifications will be seen as obvious. Examiner asserts that Applicant may supply evidence that points to a criticality of such alloy compositions that renders such modifications unobvious, or supply evidence which shows unexpected results arise when the alloys are chosen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill A. Warden/
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